Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in May 2002.

New Approvals

ANADA Number: 200-274

Pioneer Product:	034-025
Trade Name:	Lincomycin Injectable 30%
Ingredients:	Lincomycin hydrochloride
Sponsor:	Alpharma, Inc.
Approval Date:	February 1, 2002
Status:	Over-the-counter
Route:	Intramuscular
Species:	Swine
Drug Form:	Liquid (solution)
Concentration:	300 milligrams per milliliter
Indications:	For the treatment of infectious arthritis and mycoplasmal pneumonia.
Tolerance:	21CFR 556.360 Lincomycin: Tolerances for lincomycin in swine of 0.6 part per million in liver and 0.1 part per million in muscle are established. The acceptable daily intake for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.
Withdrawal:	2 days

21CFR 522.1260

NADA Number: 141-124

Trade Names:	Maxiban® plus BMD®
Ingredients:	Narasin/nicarbazin, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	January 14, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Narasin/nicarbazin - 36 grams of narasin/nicarbazin activity per pound of Type A Medicated Article; bacitracin methylene disalicylate - 10, 25, 30, 40, 50, 60 or 75 grams of bacitracin methylene disalicylate activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*. Also as aid in the control or prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.
Tolerance:	21CFR 556.428 Narasin: A tolerance for narasin in chickens is not needed. The acceptable daily intake for total residues of narasin is 5 micrograms per kilogram of body weight per day. 21CFR 556.445 Nicarbazin: A tolerance of 4 parts per million is established for residues of nicarbazin in uncooked chicken muscle, liver, skin, and kidney. 21CFR 556.70 Bacitracin: A tolerance of 0.5 part per million is established for residues of bacitracin in uncooked edible tissues and eggs of chickens. The acceptable daily intake for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day.
Withdrawal:	5 days

21CFR 558.76 and 558.366

NADA Number: 141-154

Trade Names:	Robenz® plus BMD®
Ingredients:	Robenidine hydrochloride, bacitracin methylene disalicylate
Sponsor:	Alpharma, Inc.
Approval Date:	February 11, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Broiler and fryer chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feeds.
Concentration:	Robenidine hydrochloride - 30 grams of robenidine hydrochloride activity per pound of Type A Medicated Article; bacitracin methylene disalicylate - 10, 25, 30, 40, 50, 60 or 75 grams of bacitracin methylene disalicylate activity per pound of Type A Medicated Article.
Indications:	As an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*. Also used as as aid in the control or prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.
Tolerance:	21CFR 556.70 Bacitracin: A tolerance of 0.5 part per million is established for residues of bacitracin in uncooked edible tissues and eggs of chickens. 21CFR 556.580 Robenidine: Tolerances are established for residues of robenidine hydrochloride in edible tissues of chickens as follows: 0.2 part per million in skin and fat and 0.1 part per million (negligible residue) in edible tissues other than skin and fat.
Withdrawal:	5 days

21CFR 558.515

NADA Number: 141-190

Trade Names:	Clinacox™ plus BMD® plus 3-Nitro®
Ingredients:	Diclazuril, bacitracin methylene disalicylate, roxarsone
Sponsor:	Schering-Plough Animal Health
Approval Date:	December 14, 2001
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Boiler chickens
Drug Form:	Type A Medicated Articles to make three-way combination Type C medicated feeds.
Concentration:	Diclazuril 0.91 grams activity per pound of Type A Medicated Article; bacitracin methylene disalicylate 10, 25, 30, 40, 50, 60, or 75 grams activity per pound of Type A Medicated Article; roxarsone 45.4, 90, 227, or 360 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis (mivati),* and *E. maxima.* Reduces lesion scores and improve performance and health of birds challenged with *E. maxima*. Used as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp*. or other organisms susceptible to bacitracin. Also used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium spp*. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency and improved pigmentation in broiler chickens.
Tolerance:	21CFR 556.185 Diclazuril: Tolerances are established for residues of parent diclazuril at 0.5 part per million in muscle, 3 parts per million in liver, and 1 part per million in skin/fat. 21CFR 556.70 Bacitracin: Tolerances for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate in uncooked edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and in milk and eggs is 0.5 part per million. 21CFR 556.60 Arsenic: Tolerances for total residues of combined arsenic (calculated as As) in food are established as follows: In edible tissues and in eggs of chickens and turkeys 0.5 part per million in uncooked muscle tissue, 2 parts per million in uncooked edible by-products and 0.5 part per million in eggs.
Withdrawal:	5 days

21CFR 558.76, 558.198 and *558.530*

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-185

Trade Names:	Deccox® plus Aureomycin®
Ingredients:	Decoquinate, chlortetracycline
Sponsor:	Alpharma, Inc.
Approval Date:	March 15, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Calves, beef and nonlactating dairy cattle
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Decoquinate 27.2 grams activity per pound of Type A Medicated Article; chlortetracycline 50, 90, or 100 grams activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; for the treatment of bacterial enteritis caused by *Escherichia coli,* and for bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.
Tolerance:	21CFR 556.170 Decoquinate: Tolerances are established for residues of decoquinate in the uncooked edible tissues as 1 part per million in skeletal muscle and 2 parts per million in other tissues. The acceptable daily intake for total residues of decoquinate is 75 micrograms per kilogram of body weight per day. 21CFR 556.150 Chlortetracycline: Tolerances are established for the sum of tetracycline residues in tissues of 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in kidney and fat. The acceptable daily intake for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.
Withdrawal:	Zero days

21CFR 558.195

Supplemental Approvals

NADA Number: 141-064

This supplemental application provides for additions to labeling for use in swine feed.

Trade Name:	Pulmotil® 90
Ingredients:	Tilmicosin phosphate
Sponsor:	Elanco Animal Health
Approval Date:	November 15, 2001
Status:	Veterinary Feed Directive (VFD)
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Article
Concentration:	200 grams per kilogram
Indications:	For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.
Tolerance:	21CFR 556.735 Tilmicosin: A tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) at 7.5 parts per million and in muscle at 0.1 part per million of swine.
Withdrawal:	Swine: 7 days before slaughter

21CFR 558.618

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 097-505

This supplemental application provides for the use of lincomycin in swine feed for the control of porcine proliferative enteropathies (ileitis).

Trade Names:	Lincomix® 20 Feed Medication, Lincomix® 50 Feed Medication
Ingredients:	Lincomycin hydrochloride
Sponsor:	Pharmacia & Upjohn Company
Approval Date:	February 28, 2002
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Article to make Type B or C medicated feeds.
Concentration:	Lincomycin 20 or 50 grams activity per pound of Type A Medicated Article.
Indications:	For the treatment and control of swine dysentery, for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*, for the reduction in severity of swine mycoplasma pneumonia, and for increase in rate of weight gain in growing-finishing swine.
Tolerance:	21CFR 556.360 Lincomycin: Tolerances for lincomycin in swine of 0.6 part per million in liver and 0.1 part per million in muscle are established.
Withdrawal:	6 days
Exclusivity:	3 years

21CFR 558.325

Change of Sponsor

NADA Numbers: 200-270, 200-281, 200-302

From: Blue Ridge Pharmaceuticals, Inc.
To: Virbac AH, Inc.
3200 Meacham Blvd.
Ft. Worth, TX 76137
Drug labeler code: 051311

Suitability Petition Action

Number:	02P-0189/CP1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug praziquantel which differs from the pioneer product, Droncit®, Bayer Corp., NADA 111-798, by the following characteristics: The generic product will consist of a different dosage form (solution) from the pioneer.
Action:	Filed on April 30, 2002.

Number:	02P-0198/CP1
Sponsor:	Richdel, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste, Merial Ltd., NADA 134-314, by the following characteristics: The generic product will consist of a different dosage form (gel) from the pioneer.
Action:	Filed on May 3, 2002.